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David V. Upitel 47,147  
Name of Attorney or Agent Registration No.  
David V. Upitel  
Signature of Attorney or Agent

P&G Case 8367

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :  
Benoit Ledoussal et al. : Confirmation No. 8264  
Serial No. 10/017,969 : Group Art Unit 1625  
Filed December 14, 2001 : Examiner Bernard I. Dentz

For Antimicrobial Quinolones, Their Compositions and Uses

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made below in a Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☐ 37 C.F.R. §1.97 (b)(1) - U.S. Direct (within 3-months of filing a regular application or converted provisional)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(1), is being filed within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ 37 C.F.R. §1.97 (b)(2) - Via PCT (within 3 mo. of Nat'l Stage Entry)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(2), is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application. Therefore, no fee is believed to be due.

3. ☐ 37 C.F.R. §1.97 (b)(3) - (>3 mo. after filing direct or nat'l stage entry, but before 1<sup>st</sup> O.A.)

This information disclosure statement is being submitted under 37 C.F.R. §1.97 (b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter is enclosed to facilitate charging of the fee, if necessary.

**THE FOLLOWING IS ADDITIONAL INFORMATION PERTAINING TO (2) OR (3) MARKED WITH AN (X) ABOVE.**

(a) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that both a copy of the International Search Report and copies of the references cited therein are present in the national stage file. In accordance with MPEP §1893.03(g), it is respectfully requested that the Examiner note the consideration of these references in the first Office Action via the PTO-892 form.

(b) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that a copy of the International Search Report is present in the national stage file. Copies of the references cited in that report are enclosed.

(c) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 does not indicate that a copy of the International Search Report and copies of the references cited are present in the national stage file. Copies of the International Search Report and references are attached.

4. ☐ 37 C.F.R. §1.97 (b)(4) - (before the mailing of a first Office Action after the filing of a request for continued examination under §1.114)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(4), is being filed with the Request for Continued Examination (RCE) under 37 C.F.R. §1.114.

5. ☐ Information to be Considered with CPA Filing. This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 CFR 1.53(d).

6. ☒ 37 C.F.R. §1.97(c) with fee payment - (use after 1<sup>st</sup> Office Action & before Final Office Action or Notice of Allowance)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter is enclosed to facilitate the charging of the fee.

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

☐ (1) Copies of the cited references were previously cited by or submitted to the USPTO in prior application Case No. \_\_\_\_, U.S. Patent Application Serial No. \_\_, filed \_\_. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of those documents are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d).

OR

☒ (2) Copies of the cited documents are enclosed.

OR

☐ (3) Copies of all said documents, except document No.'s \_\_\_\_, were submitted and considered in parent application U.S. Patent Application Serial No. \_\_\_\_, filed \_\_\_\_\_. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of document No.'s \_\_\_\_ are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of document No.'s \_\_\_\_ are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (4) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (5) Applicants also respectfully request the Examiner to consider and make of record the copending applications listed on the attached page.



Additional information is attached.

Respectfully submitted,

By David V. Upton  
David V. Upton  
Attorney or Agent for Applicant(s)  
Registration No. 47,147  
(513) 622-1825

Date: July 24, 2002

Customer No. 27752

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

SHEET 1 of 4

Application Number	10,017,969
Confirmation Number	8264
Filing Date	December 14, 2002
First Named Inventor	Benoit Ledoussal
Group Art Unit	1625
Examiner Name	Bernard I. Dentz
Attorney Docket Number	8367

## U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	U.S. PATENT DOCUMENT Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,844,902		Grohe	07/04/1989	
	2	5,072,001		Hagen et al.	12/10/1991	
	3	5,328,908		Demuth, Jr. et al.	07/12/1994	
	4	5,457,104		Bartel et al.	10/10/1995	
	5	5,556,979		Phillips et al.	09/17/1996	
	6	5,599,816		Chu et al.	02/04/1997	
	7	5,726,182		Chu et al.	03/10/1998	
	8	5,580,872		Chu et al.	12/03/1996	
	9	5,229,396		Brighty	07/20/1993	
	10	5,412,1098		Yasuhiro et al.	05/02/1995	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	FOREIGN PATENT DOCUMENT Office <sup>3</sup> Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	11	EP 0572259	A1	UBE Industries, Ltd.	01/12/1993		
	12	EP 0775702	A1	Toyama Chemical Co., Ltd.	05/28/1997		
	13	EP 0308019	A2	Merck & Co., Inc.	03/22/1989		
	14	EP 0413455	B2	Pfizer Inc.	07/30/1990		
	15	EP 0947513	A1	Daiichi Pharm. Co. Ltd.	10/23/1997		
	16	WO 99/07696	A1	Korea Research Institute of Chemical Technology	02/18/1999		
	17	WO 91/16894	A1	Abbott Laboratories	11/14/1991		
	18	WO 95/10519	A1	Abbott Laboratories	04/20/1995		
	19	WO 98/54169	A <sup>*</sup>	Daiichi Pharm. Co. Ltd.	05/30/1997		
	20	WO 98/52939	A1	Daiichi Pharm. Co. Ltd.	05/29/1997		
	21	FR 2656-611	A1		07/05/1991		
	22	JP 09002953		Chugai Pharmaceut Co. Ltd.*	07/01/1997		
	23	JP 62-255,482		Kyorin Seiyaku K. K.	11/07/1987		
	24	JP 03-115,277		Banyu Pharm Co., Ltd.	05/16/1991		
	25	JP 09-136,886		Daiichi Saiyaku Co., Ltd.	05/27/1997		
	26	JP D10,287,669		Daiichi Saiyaku Co., Ltd.	10/27/1998		

Abstract

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	Application Number	10,017,969
	Confirmation Number	8264
	Filing Date	December 14, 2002
	First Named Inventor	Benoit Ledoussal
	Group Art Unit	1625
	Examiner Name	Bernard I. Dentz
	Attorney Docket Number	8367

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### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
	27	ALBRECHT, "Development of Antibacterial Agents of the Nalidixic Acid Type", <u>Prog. In Drug Research</u> , 1977, p. 9-104, Vol. 21.	
	28	WOLFSON et al., "The Fluoroquinolones: Structures, Mechanisms of Action and Resistance, and Spectra of Activity In Vitro", <u>Antimicrobial Agents and Chemotherapy</u> , 1985, p. 581-586, Vol. 28, No. 4.	
	29	KLOPMAN et al., "Computer Automated Structure Evaluation of Quinolone Antibacterial Agents", <u>Antimicrobial Agents and Chemotherapy</u> , 1987, p. 1831-1840, Vol. 31, No. 11.	
	30	WENTLAND et al., "Quinolone Antibacterial Agents", <u>Annual Reports in Medicinal Chemistry</u> , 1986, p. 145-154, Vol. 20, Chapter 15.	
	31	CORNETT et al., "Quinolone Antibacterial Agents", <u>Annual Reports in Medicinal Chemistry</u> , 1986, p. 139-148, Vol. 21, Chapter 14.	
	32	WHITE et al., "Quinolones", <u>Annual Reports in Medicinal Chemistry</u> , 1987, p. 117-126, Vol. 22, Chapter 12, Section III - Chemotherapeutic Agents.	

EXAMINER

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	Application Number	10,017,969
	Confirmation Number	8264
	Filing Date	December 14, 2002
	First Named Inventor	Benoit Ledoussal
	Group Art Unit	1625
	Examiner Name	Bernard I. Dentz
	Attorney Docket Number	8367

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	33	KOGA et al., "Structure-Activity Relationships of Antibacterial 6,7- and 7,8-Disubstituted 1-alkyl-1,4-dihydro-4-oxoquinoline-3-carboxylic Acids", J. Med. Chem., 1980, p. 1358-1363, Vol. 23.	
	34	DOMAGALA et al., "1-Substituted 7-[3-(Ethylamino)methyl]-1-pyrrolidinyl]-6,8-difluoro-4-oxo-3-quinolinecarboxylic Acids. New Quantitative Structure-Activity Relationships at N <sub>1</sub> for the Quinolone Antibacterials", J. Med. Chem., 1988, p. 991-1001, Vol. 31.	
	35	ROSEN et al., "Asymmetric Synthesis and Properties of the Enantiomers of the Antibacterial Agent 7-(3-Aminopyrrolidin-1-yl)-1-(2,4-difluorophenyl)-1,4-dihydro-6-fluoro-4-oxo-1,8-naphthyridine-3-carboxylic Acid Hydrochloride", J. Med. Chem., 1988, p. 1586-1590, Vol. 31.	
	36	ROSEN et al., "Design, Synthesis, and Properties of (4S)-7-(4-Amio-2-substituted-pyrrolidin-1-yl)quinolone-3-carboxylic Acids", J. Med. Chem., 1988, p. 1598-161, Vol. 31.	
	37	LEDOUSSAL et al., "Potent Non 6-Fluoro Substituted Quinolone Antibacterials: Synthesis and Biological Activity", J. Med. Chem., 1992, p. 198-200, Vol. 35.	
	38	DONAGALA et al., "Quinolone Antibacterials Containing the New 7-[3-(1-Aminoethyl)-1-pyrrolidinyl] Side Chain: The Effects of the 1-Aminoethyl Moiety and Its Stereochemical Configurations on Potency and in Vivo Efficacy", J. Med. Chem., 1993, p. 871-882, Vol. 36, No.7.	
EXAMINER		DATE CONSIDERED	

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	Application Number	10,017,969
	Confirmation Number	8264
	Filing Date	December 14, 2002
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	39	HAGEN et al., "Synthesis and Antibacterial Activity of New Quinolones Containing a 7-[3-(1-Amino-1-methylethyl)-1-pyrrolidinyl] Moiety. Gram-Positive Agents with Excellent Oral Activity and Low Side Effect Potential", J. Med. Chem., 1994, p. 733-738, Vol. 37, No.6.	
	40	CECCHETTI et al., "Studies on 6-Aminoquinolones: Synthesis and Antibacterial Evaluation of 6-Amino-8-methylquinolones", J. Med. Chem., 1996, p. 436-445, Vol. 39, No.2.	
	41	CECCHETTI et al., "Potent 6-Desfluoro-8-methylquinolones as New Lead Compounds in antibacterial Chemotherapy", J. Med. Chem., 1996, p. 4952-4957, Vol. 39, No.25.	
	42	HONG et al., "Novel 5-Amino-6-Methylquinolone Antibacterials: A New Class of Non-6-Fluoroquinolones", Bioorganic & Medicinal Chem Letts., 1997, p. 1875-1878, Vol. 7, No. 14.	
	43	GUN et al., "Synthesis and Structure - Activity Relationships of 2-Pyridones: A Novel Series of Potent DNA Gyrase Inhibitors as Antibacterial Agents", J. Med. Chem., 1996, p. 3070-3088, Vol. 39.	
	44	SANDERS et al., "Inducible $\beta$ -Lactamases: Clinical and Epidemiologic Implications for Use of New $\beta$ -Lactam Cephalosporins", Reviews of Infectious Diseases, July-August 1988, p. 830-838, Vol. 10, No. 4.	
	45	MA et al., "Synthesis and Antimicrobial Activity of 4H-4-Oxoquinolizine Derivatives: Consequences of Structural Modification at the C-8 Position", J. Med. Chem., 1999, p. 4202-4213, Vol. 42, No. 20.	

EXAMINER	DATE CONSIDERED
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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